AO 120 (Rev. 3/04)

TO:	REPORT ON THE FILING OR DETERMINATION OF AN ACTION REGARDING A PATENT OR TRADEMARK
Mail Stop 8 Director of the U.S. Patent and Trademark Office P.O. Box 1450 Alexandria, VA 22313-1450	

In Compliance with 35 U.S.C. § 290 and/or 15 U.S.C. § 1116 you are hereby advised that a court action has been filed in the U.S. District Court TRENTON on the following ☑ Patents or ☐ Trademarks:

DOCKET NO.	DATE FILED	U.S. DISTRICT COURT
08-2892 (JAP)	6/9/2008	TRENTON

PLAINTIFF	DEFENDANT
JANSSEN L.P. JANSSEN PHARMACEUTICA N.V. ORTHO-MCNEIL NEUROLOGICS, INC.	SANDOZ, INC.

	PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1	7,160,559		SEE ATTACHED COMPLAINT
2	4,663,318		
3			
4			
5			

In the above—entitled case, the following patent(s)/ trademark(s) have been included:

DATE INCLUDED	INCLUDED BY ☐ Amendment ☐ Answer ☐ Cross Bill ☐ Other Pleading	
PATENT OR TRADEMARK NO.	DATE OF PATENT OR TRADEMARK	HOLDER OF PATENT OR TRADEMARK
1		
2		
3		
4		
5		

In the above—entitled case, the following decision has been rendered or judgement issued:

DECISION/JUDGEMENT

CLERK	(BY) DEPUTY CLERK	DATE
WILLIAM T. WALSH, CLERK		6/12/2008

Copy 1—Upon initiation of action, mail this copy to Director Copy 3—Upon termination of action, mail this copy to Director
Copy 2—Upon filing document adding patent(s), mail this copy to Director Copy 4—Case file copy

for which RAZADYNE ER® is approved fall within one or more of the claims of the '559 patent.

29. Sandoz is liable for infringement of the '559 patent under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing ANDA No. 78-685 with a paragraph IV certification seeking FDA approval of ANDA No. 78-685 prior to expiration of the '559 patent.

30. The product for which Sandoz seeks approval in its ANDA No. 78-685 falls within one or more of the claims of the '559 patent. If approved, the manufacture, use, offer for sale, and sale in the United States, and importation into the United States of Sandoz's proposed galantamine hydrobromide product would infringe one or more of the claims of the '559 patent.

31. Upon information and belief, if ANDA No. 78-685 is approved, Sandoz intends to manufacture, use, offer for sale, and sell in the United States, and import into the United States, the galantamine hydrobromide product for which approval is sought in Sandoz's ANDA No. 78-685.

32. The manufacture, use, offer for sale and sale in the United States, and importation into the United States of Sandoz's proposed galantamine hydrobromide product would infringe one or more claims of the '559 patent, and Sandoz would be liable for direct infringement under 35 U.S.C. § 271(a).

33. Upon information and belief, the conditions of use for which Sandoz seeks approval in its ANDA No. 78-685 fall within one or more of the claims of the '559 patent. Upon information and belief, if approved, use of Sandoz's proposed

galantamine hydrobromide product in accordance with the proposed labeling submitted in ANDA No. 78-685 would infringe one or more of the claims of the '559 patent.

34. Upon information and belief, if approved, Sandoz's galantamine hydrobromide products for which approval is sought in Sandoz ANDA No. 78-685 will be administered to human patients in a therapeutically effective amount for treatment of dementia of the Alzheimer's type, which administration would constitute direct infringement of one or more claims of the '559 patent. Upon information and belief, this infringement will occur at Sandoz's behest, with its intent, knowledge, and encouragement, and Sandoz will actively induce, encourage, aid, and abet this administration with knowledge that it is in contravention of Janssen's rights under the '559 patent.

35. Sandoz's manufacture, use, offer for sale or sale in the United States, or importation into the United States, prior to expiration of the '559 patent, of the galantamine hydrobromide product for which approval is sought in ANDA No. 78-685, would actively induce and contribute to infringement of the '559 patent, and Sandoz Pharmaceutical would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or (c).

36. Sandoz's infringement of the '559 patent has been, and continues to be, willful.

37. Janssen will be irreparably harmed if Sandoz is not enjoined from infringing or actively inducing or contributing to infringement of the '559 patent. Janssen does not have an adequate remedy at law.

Prayer For Relief

WHEREFORE, Plaintiffs seek the following relief:

A. A judgment that Sandoz has infringed the '559 patent under 35 U.S.C. § 271(e)(2)(A), and that such infringement is willful;

B. A judgment and order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of the Sandoz ANDA No. 78-685 for galantamine hydrobromide extended-release Eq. 8 mg base, 16 mg base, and 24 mg base capsules be not earlier than the expiration date of the '559 patent;

C. A judgment declaring that Sandoz's manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of the galantamine hydrobromide products for which approval is sought in ANDA No. 78-685 would constitute infringement of the '559 patent, or would induce or contribute to such infringement, pursuant to 35 U.S.C. § 271 (a), (b), and/or (c);

D. A permanent injunction enjoining Sandoz and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making, using, selling, or offering to sell in the United States, or importing into the United States, the galantamine hydrobromide extended-release capsules for which approval is sought in ANDA No. 78-685, or any galantamine hydrobromide product that infringes or induces or contributes to the infringement of the '559 patent, until expiration of that patent;

E. A finding that this is an exceptional case, and an award of attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. An award of costs and expenses in this action; and

G. Such further and other relief as this Court determines to be just and proper.

s/Thomas E. Hastings
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DATED: June 9, 2008

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

I hereby certify that to my knowledge the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. It is, however, related to two other cases pending in this forum. One of these cases is *Janssen, L.P., et al. v. Barr Laboratories, Inc. et al*, Civil Action No. 07-1515 (JAP), presently pending in the United States District Court for the District of New Jersey. In Civil Action No. 07-1515, Janssen has alleged that Barr, by filing its ANDA No. 78-189, has infringed United States Patent No. 7,160,559 (the same patent at issue here). The other case is *Janssen, L.P., et al. v. KV Pharmaceuticals, Inc.*, Civil Action No. 07-5982 (JAP), presently pending in the United States District Court for the District of New Jersey. In Civil Action No. 07-5982, Janssen has alleged that KV, by filing its ANDA No. 78-198, has infringed United States Patent No. 7,160,559 (the same patent at issue here).

s/Thomas E. Hastings

Dated: June 9, 2008

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

JANSSEN, L.P., JANSSEN PHARMACEUTICA N.V., and ORTHO-MCNEIL NEUROLOGICS, INC., Plaintiffs, v. SANDOZ, INC. Defendant.	Civ. Action No._____ **COMPLAINT FOR PATENT INFRINGEMENT** Filed Electronically

Plaintiffs Janssen, L.P., Janssen Pharmaceutica N.V., and Ortho-McNeil Neurologics, Inc. (collectively, "Janssen"), by their attorneys, for their complaint against Sandoz, Inc., allege as follows:

The Parties

1. Plaintiff Janssen, L.P., a wholly owned subsidiary of Johnson & Johnson, is a limited partnership organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

2. Plaintiff Janssen Pharmaceutica N.V., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of Belgium and has its principal place of business at Turnhoutseweg 30, B-2340 Beerse, Belgium.

3. Plaintiff Ortho-McNeil Neurologics, Inc., a wholly owned subsidiary of Johnson & Johnson, is a corporation organized and existing under the laws of the State of New Jersey and has its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

4. Upon information and belief, Defendant Sandoz, Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado and has a principal place of business at 506 Carnegie Center, Ste. 400, Princeton, New Jersey 08540-6243. Upon information and belief, Sandoz is registered to do business in New Jersey and does do business in New Jersey. Sandoz also maintains a registered agent in New Jersey for the receipt of service of process at Prentice Hall Corp. System, 830 Bear Tavern Road, Trenton, NJ 08628.

5. Upon information and belief, Sandoz is in the business of manufacturing, distributing, and selling generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies and sold by Sandoz pursuant to an approved abbreviated new drug application. Sandoz

manufactures, markets, and sells many pharmaceuticals products, including numerous generic prescription drug products, that are marketed and sold to customers in the State of New Jersey and that are registered in the New Jersey Generic Formulary of the New Jersey Department of Health and Human Services.

6. Sandoz prepared and filed with the FDA, pursuant to 21 U.S.C. 355(j), ANDA No. 78-685 concerning galantamine hydrobromide extended-release capsules and seeks approval of that application from the Food and Drug Administration ("FDA"). Upon information and belief, if ANDA No. 78-685 is approved, it is the intention of Sandoz to commercially manufacture, use, and sell Sandoz's proposed galantamine hydrobromide extended-release capsules in the United States.

Jurisdiction and Venue

7. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, for infringement of United States Patent No. 7,160,559 ("the '559 patent"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. Sandoz is subject to personal jurisdiction in this judicial district because it is currently registered in the State of New Jersey to do business and does business in the State of New Jersey and, on information and belief, maintains a registered agent in New Jersey for the receipt of service of process at Prentice Hall Corp. System, 830 Bear Tavern Road, Trenton, NJ 08628, and by virtue of, *inter alia*, its having conducted business in the State of New Jersey, having availed itself of the rights and benefits of New Jersey law, and having engaged in substantial and continuing contacts with the State. In addition, upon information and belief, Sandoz has availed itself of the

benefits of this forum. For example, Sandoz has previously submitted to the jurisdiction of this Court by filing suit and by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, Sandoz filed suit in *Sandoz, Inc. v. Eli Lilly and Company*, 07-cv-04100 (D.N.J.), and Sandoz consented to jurisdiction and filed counterclaims in *Janssen Pharmaceutica N.V., et al. v. Sandoz, Inc.*, Civil Action No. 07-2058 (JAP) (JJH), *Otsuka Pharmaceutical Co., Ltd. v. Sandoz, Inc.*, 07-cv-01000 (D.N.J.) and *Sepracor Inc. et al. v. Sandoz, Inc.*, 07-cv-6107 (D.N.J.).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

Regulatory Requirements for Approval of New and Generic Drugs

10. Any person wishing to market a pioneering drug – that is, a new drug that has not previously been approved by FDA – must first file a New Drug Application ("NDA") with FDA demonstrating that the drug is safe and effective for its intended use. 21 U.S.C. § 355(b). To secure approval of a NDA, the NDA applicant must, among other things, collect and submit to FDA extensive animal and human clinical trial data at a substantial cost of time and money.

11. A person wishing to market a generic copy of a pioneering drug that previously has been approved by FDA may follow a truncated approval process by filing an abbreviated new drug application for a generic version of the drug. In the ANDA, the applicant must demonstrate, among other things, bioequivalence of the generic copy of the pioneering drug. 21 U.S.C. § 355(j)(2)(A)(iv). To demonstrate bioequivalence, the ANDA applicant must show that the rate and extent of absorption of the therapeutic ingredient in the generic drug does not significantly differ from that in the

pioneering drug, or, if the rate of absorption differs, that such difference is intentional, is reflected in the proposed labeling, is not essential to the attainment of effective body drug concentrations on chronic use, and is considered medically insignificant for the drug. 21 U.S.C. § 355(j)(8)(B).

12. However, unlike an NDA applicant, an ANDA applicant is not required to include safety and effectiveness data. The ANDA applicant is not required, for example, to conduct well-controlled clinical trials concerning the safety and effectiveness of the proposed drug. Instead, the ANDA applicant is permitted to piggy-back on the safety and effectiveness data developed and submitted by the approved NDA holder. 21 U.S.C. § 355(j).

13. Nor does an ANDA applicant establish any new conditions of use for the proposed drug product. Instead, an ANDA applicant may seek approval only for conditions of use that previously have been approved in connection with an approved NDA. 21 U.S.C. § 355(j)(2)(A)(i).

14. No person may market in the United States a new drug without an approved NDA or a generic version of a drug without an approved ANDA. 21 U.S.C. § 355(a).

Plaintiffs' Approved Drug Product

15. Janssen is the holder of an approved new drug application, NDA No. 21-615, for galantamine hydrobromide extended-release capsules. That NDA was approved by FDA on April 1, 2005 and covers three strengths of capsule – Eq. 8 mg base, 16 mg base, and 24 mg base. The sole indication or condition of use for which

galantamine hydrobromide extended release capsules are approved in NDA No. 21-615 is the treatment of mild to moderate dementia of the Alzheimer's type.

16. Pursuant to FDA's approval, Janssen currently markets galantamine hydrobromide extended-release capsules for the treatment of mild to moderate dementia of the Alzheimer's type under the trademark RAZADYNE ER®. Until 2005, Janssen marketed its galantamine hydrobromide products under the trademark REMINYL®.

17. FDA has listed the '559 patent in the Orange Book – formally known as Approved Drug Products With Therapeutic Equivalence Evaluations – in connection with NDA No. 21-615.

18. The '559 patent qualifies for listing in the Orange Book in connection with NDA No. 21-615 because it claims an approved use of the drug product that is the subject of that NDA. Sandoz has never challenged the listing of the '559 patent in the Orange Book.

Sandoz's ANDA

19. Upon information and belief, Sandoz has represented that on or before March 20, 2007, it submitted to FDA an ANDA (ANDA No. 78-685) a paragraph III certification under section 505(j)(2)(A)(vii)(III) Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j)(2)(A)(vii)(IIII) as to the '559 patent, and a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(III) as to United States Patent No. 4,663,318 ("the '318 patent"), for galantamine hydrobromide extended-release capsules purportedly bioequivalent to Plaintiffs' RAZADYNE ER® products. The purpose of Sandoz's ANDA and paragraph

IV certification is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide extended-release capsules.

20. On May 2, 2007, Janssen brought suit against Sandoz, Inc. alleging infringement of the '318 patent. *See Janssen Pharmaceutica N.V., et al. v. Sandoz, Inc.*, Civil Action No. 07-2058 (JAP) (JJH). That case is presently stayed pending the resolution of the matter of *In re: '318 Patent Infringement Litigation,* Case No. 05-356 (consolidated) (SLR) pending before Judge Sue L. Robinson in the United States District Court for the District of Delaware.

21. Upon information and belief, Sandoz has represented that on or before April 25, 2008, it converted its paragraph III certification as to the '559 patent into a paragraph IV certification under section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), for galantamine hydrobromide extended-release capsules purportedly bioequivalent to Janssen's RAZADYNE ER® products. The purpose of Sandoz's ANDA and paragraph IV certifications, is to obtain approval under section 505(j) of the FDCA to engage in the commercial manufacture and sale of its proposed galantamine hydrobromide extended-release capsules before the expiration of the patents listed in the Orange Book for Janssen's NDA No. 21-615. Hence, Sandoz's purpose in submitting ANDA No. 78-685 is to market in the United States the galantamine hydrobromide products described therein before expiration of the '559 patent.

22. On or about April 25, 2008, Sandoz sent a letter advising Janssen of Sandoz's paragraph IV certification relating to the '559 patent ("Sandoz's Notice Letter").

23. Upon information and belief, the sole condition of use for which Sandoz seeks approval in its ANDA No. 78-685 for its proposed galantamine hydrobromide extended-release capsules is the treatment of mild to moderate dementia of the Alzheimer's type, the same condition of use as that approved in Janssen's NDA No. 21-615.

24. Upon information and belief, the sole indication set forth in the proposed labeling submitted by Sandoz in its ANDA No. 78-685 for its proposed galantamine hydrobromide extended-release capsules is the treatment of mild to moderate dementia of the Alzheimer's type, the same indication as that set forth in the approved labeling for Janssen's RAZADYNE ER® capsules.

Count 1: Patent Infringement

25. Janssen realleges paragraphs 1 through 24 above as if fully set forth herein.

26. On January 9, 2007, the United States Patent and Trademark Office duly and legally issued the '559 patent, entitled "Controlled Release Galantamine Formulation." The term of the '559 patent runs through December 20, 2019. A true and correct copy of the '559 patent is attached hereto as Exhibit A.

27. Janssen is the owner of the '559 patent.

28. Janssen currently markets galantamine hydrobromide extended-release capsules in the United States under the trademark RAZADYNE ER® and previously marketed its galantamine hydrobromide products in the United States under the trademark REMINYL®. The product RAZADYNE ER® and the conditions of use